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| 10/825,494 | 04/15/2004 | Joel Q. Xue | 140823IT (5024-00120) | 8563 |

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| EXAMINER | |
|---|---|
| PATEL, NATASHA | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/825,494 | XUE ET AL. | |
| | Examiner | Art Unit | |
| | Natasha N. Patel | 3766 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *rce filed 9/26/07*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

The RCE filed on 9/26/2007 has been received and considered. By this amendment, Claims 1, 16, and 20 have been amended. No claims have been cancelled or added. Thus, Claims 1-20 are pending in the application.

### *Response to Arguments*

1. Applicant's arguments with respect to claims 1-20 have been considered but are moot in view of the new ground(s) of rejection.

### *Claim Rejections - 35 USC § 103*

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1 and 2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fishler et al. (US Patent 7,069,069) in view of Mann et al. (US Patent 5,514,164).

4. Regarding Claim 1, Fishler discloses a method of detecting cardiac repolarization abnormality using at least one electrocardiogram signal (see Abstract), the method comprising: deriving a total quantity of representative beats of the at least one electrocardiogram signal; using at least one morphology shape descriptor to determine a total quantity of values (see morphology measurement data) representing the total quantity of representative beats (see col. 2, lines 21-25), wherein the morphology shape descriptor utilizes any one of the following morphology features to determine the total quantity; a maximum morphology feature; minimum morphology feature; area

morphology feature; amplitude morphology feature; slope morphology feature; time interval morphology feature (see col. 2, lines 39-46); and using data corresponding to at least some of the total quantity of values to assess cardiac repolarization abnormality (see col. 2. lines 14-18). The examiner considers that the beats that are derived from the ECG signal are representative beats because they are selected (see col. 2, line 24). Finally, the examiner considers that an indication of heart failure will necessarily indicate an abnormality in cardiac repolarization. Although Fishler determines morphology measurements from an electrogram instead of an electrocardiogram, it would have been a matter of obvious design choice for one of ordinary skill in the art at the time of the invention as to what method of obtaining cardiac electrical data to use. The applicant does not disclose any criticality to using an external device as opposed to an internal device and an internal device would work equally well at deriving the desired data from the heart. For example, Mann teaches that both an ECG and an EGM provide information about repolarization (see col. 1, lines 43-62). Finally, although Fishler does not set out to only detect cardiac repolarization abnormalities, his investigation of CHF includes detecting or not detecting cardiac repolarization since CHF would cause some abnormal repolarization.

5. Regarding Claim 2, Fishler discloses that the total quantity of representative beats comprises at least one beat representative of each lead of the at least one electrocardiogram signal (see col. 5, lines 20-34). The examiner considers since the two leads record two separate electrocardiograms and both electrocardiograms are utilized, then representative beats from both leads are present in the sample.

6. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schroeppel et al. (US Patent 6,571,122) in view of Mann et al. (US Patent 5,514,164).

7. Regarding Claim 1, Schroeppel discloses a method of detecting cardiac repolarization abnormality using at least one electrocardiogram signal (see Abstract), the method comprising: deriving a total quantity of representative beats of the at least one electrocardiogram signal (see col. 3, lines 25-27); using at least one morphology shape descriptor to determine a total quantity of values representing the total quantity of representative beats (see col. 4, lines 11-21), wherein the morphology shape descriptor utilizes any one of the following morphology features to determine the total quantity; a maximum morphology feature; minimum morphology feature; area morphology feature; amplitude morphology feature; slope morphology feature; time interval morphology feature (see time intervals occurring between successive heart beats; col. 4, lines 12-16); and using data corresponding to at least some of the total quantity of values to assess cardiac repolarization abnormality (see col. 4, lines 21-24). The examiner considers an abnormal heart variability is the result of an abnormal cardiac repolarization. Although Schroeppel determines morphology measurements from an electrogram instead of an electrocardiogram, it would have been a matter of obvious design choice for one of ordinary skill in the art at the time of the invention as to what method of obtaining cardiac electrical data to use. The applicant does not disclose any criticality to using an external device as opposed to an internal device and an internal device would work equally well at deriving the desired data from the heart. For example,

Mann teaches that both an ECG and an EGM provide information about repolarization (see col. 1, lines 43-62). Finally, although Schroeppel does not set out to only detect cardiac repolarization abnormalities, his investigation of abnormal heart variability includes detecting or not detecting cardiac repolarization since abnormal heart variability would cause some abnormal repolarization.

8. Claims 1, 3, 6, 15, 16, and 20 are rejected under 103(a) as being unpatentable over Reinhold et al. (US Patent 4,531,527) in view of Paine et al. (US Patent 3,638,066).

9. Regarding Claims 1 and 20, Reinhold discloses a method of detecting cardiac repolarization abnormality using at least one electrocardiogram signal (see col. 5, lines 19-21), the method comprising: deriving a total quantity of representative beats (see col. 7, lines 28-34) of the at least one electrocardiogram signal (see col. 4, lines 30-40); and using at least one morphology shape descriptor to determine a total quantity of values representing the total quantity of representative beats (see col. 9, line 55- col. 10, line 10); and using data corresponding to at least some of the total quantity of values to assess cardiac repolarization abnormality (see col. 10, lines 23-28). The examiner considers that an arrhythmia is a cardiac repolarization abnormality. Reinhold's focus on the QRS segment does in fact include repolarization. Paine points out that the QRS complex is the sum of ventricular depolarization and atrial repolarization (see col. 1, lines 32-52). Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to evaluate atrial repolarization using the QRS segment since Paine discloses that the QRS segment includes repolarization (see col. 1, lines 32-52).

10. Regarding Claim 3, Reinhold discloses a template (see col. 9, line 66-col. 10, line 13 and col. 20, lines 14-16). Reinhold further discloses generating a template using at least one value (data) corresponding to at least one of the representative beats (see col. 10, lines 6-10). The examiner considers that the beat that is sufficiently different from all the templates is one of the representative beats to which the template is being compared (see col. 10, lines 3-6). Finally, the examiner considers that the comparison is used to determine a cardiac repolarization because the template classifies the ECG signals and the classification includes an 'alarm' criteria in the case of an abnormal cardiac repolarization (see col. 10, lines 45-47).

11. Regarding Claim 6, Reinhold discloses altering the template based at least in part on the at least one value corresponding to the at least one other of the representative beats (see col. 10, lines 6-10). The examiner considers that if the monitor comes across a new 'sufficiently different beat,' then the template will be changed once again.

12. Regarding Claim 15, Reinhold discloses displaying data corresponding to at least one electrocardiogram signal (col. 11, lines 44-46). ST segments correspond to the ECG and office unit displays this data.

13. Regarding Claim 16, see rejection of similarly worded Claims 1 and 3 above.

14. Claims 2 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reinhold et al. (US Patent 4,531,527) and Paine et al. (US Patent 3,638,066), as applied to Claim 1 above, in view of Steinhaus et al. (US Patent 5,215,098).

15. Regarding Claims 2 and 17, Reinhold discloses leads carrying electrocardiogram signals (see col. 14, lines 37-47 and Figure 3). Reinhold does not disclose that a beat from each lead makes up the total quantity of representative beats. Steinhaus discloses a similar detection system (see col. 18, lines 56-53) that the total quantity of representative beats comprises at least one beat representative of each lead (10) of the at least one electrocardiogram signal (see col. 5, lines 35-40 and Figure 1). The examiner considers that since all the leads are represented by line 10 and line 10 goes directly from the heart to the correlator 5, then the beats collected by each lead are all going into the correlator. It would have been obvious to one of ordinary skill in the art at the time of the invention to create a sample using beats from each of the leads as taught by Steinhaus in order to reduce the influence of errors that may be caused by something other than the heart, for example a lead dysfunction.

16. Claims 4-5, 7 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reinhold et al. (US Patent 4,531,527) and Paine et al. (US Patent 3,638,066), as applied to Claim 1 above, in view of Cohen et al. (US Patent 4,802,491).

17. Regarding Claim 4, Reinhold discloses comparing the ECG samples to the template (see col. 10, lines 3-6). Reinhold does not disclose a threshold. Cohen discloses that a similar cardiac monitor in which cardiac repolarization abnormality exists if a variation between the template and the at least one value corresponding to at least one other of the representative beats is greater than a threshold value (see col. 9, lines 48-52). It would have been obvious to one of ordinary skill in the art at the time of

the invention to use thresholds with the template comparison in order to catch more subtle changes (see col. 9, lines 43-45) as taught by Cohen.

18. Regarding Claim 5, Cohen discloses adjusting the alternation energy based at least in part on a level of noise in the at least one electrocardiogram signal (see col. 7, lines 10-23). Cohen does not disclose adjusting the threshold value due to the level of noise. However, it is well known and common in signal processing to adjust values to accommodate for noise. Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to adjust the threshold value based on the level of noise, especially since the other values, which are being compared to the threshold value, have been adjusted under the same circumstances. Being consistent in this manner, allows for a more accurate comparison between the ECG signal values and the threshold.

19. Regarding Claim 7, Reinhold does not elaborate on the signal processing techniques. Cohen discloses a similar monitoring device, which normalizes at least some of the values of the total quantity of values (see col. 2, lines 17-21). It would have been obvious to one of ordinary skill in the art at the time of the invention to normalize the values gathered in Reinhold's invention because it is a well known and common signal processing technique.

20. Regarding Claim 11, Cohen discloses tagging at least one value of the total quantity of values with a marker (see col. 2, lines 50-54). Once again, it is common to tag specific values in a string of values as a means of organizing the data and quickly finding values of importance at a later time.

21. Claims 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reinhold et al. (US Patent 4,531,527) and Paine et al. (US Patent 3,638,066), as applied to Claim 1 above, in view of Cohen et al. (US Patent 4,802,491) and Thiagarajan et al. (US Patent 6,983,183).

22. Regarding Claim 12, Cohen discloses a marker (see col. 3, lines 40-44), but he does not disclose that the marker is a measurement that does not change over time. Thiagarajan discloses a marker that does not change over time (see col. 6, lines 8-13). The position and magnitude of the R-wave is a measurement that will not change considerably over time. Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to use such a marker to detect abnormalities in the ECG signals to be evaluated for cardiac repolarization.

23. Regarding Claim 13, Cohen discloses that the marker is a measurement that changes over time (see col. 3, lines 40-44). The examiner considers that the different values are indicative of changing measurements and 'one particular time in its evolution' refers to a constant time interval at which these measurements are taken.

24. Regarding Claim 14, Cohen discloses using the marker as part of a discriminator of cardiac repolarization abnormality (see col. 3, lines 26-29). The marker-based analysis procedure described helps to detect and quantify alternation in waveform morphology. The examiner believes since alternation indicates repolarization abnormalities, the marker-based analysis is essentially indicating repolarization abnormalities.

25. Claims 8 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reinhold et al. (US Patent 4,531,527) and Paine et al. (US Patent 3,638,066), as applied to Claim 1 above, in view of Arnold et al. (US Patent 5,713,367).

26. Regarding Claims 8 and 18, Reinhold discloses the selection and analysis of appropriate data segments (see col. 7, lines 35-50 and col. 11, lines 42-47). However, Reinhold does not elaborate on the selection process. Arnold discloses a first electrocardiogram signal representative of a first duration of time and a second electrocardiogram signal representative of a second duration of time, and wherein the first duration of time and the second duration of time are non-continuous (see col. 5, lines 42-52). The examiner considers that the characterization of only portions of the recorded ECG data means that there will be a portion of the signal representing one duration of time and another portion of the signal representing another duration of time. The examiner considers that a portion of a signal is still a signal. It would have been obvious to one of ordinary skill in the art at the time of the invention to select various segments of the ECG signals for analysis since choosing two contiguous segments may inadvertently increase the chances of not noticing an abnormality.

27. Claims 9-10 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reinhold et al. (US Patent 4,531,527) and Paine et al. (US Patent 3,638,066), in view of Arnold et al. (US Patent 5,713,367) and further in view of DePasquale et al. (US Patent 6,847,840).

28. Regarding Claims 9 and 19, Arnold discloses administering a pharmacological agent that stresses the heart of the patient (see col. 3, lines 52-56) and obtaining an

ECG signal (see col. 10, lines 10-23). Arnold does not disclose determining variations between ECG signals before and after administering the drug. DePasquale discloses introducing pharmacological intervention; obtaining the at least one electrocardiogram signal from the patient, the at least one electrocardiogram signal comprising a first electrocardiogram signal comprising beats prior to the administration of the pharmaceutical drug (see pre-dose curve) and a second electrocardiogram signal comprising beats after the administration of the pharmaceutical drug (see post-dose curve); and determining a variation between values of the total quantity of values that correspond to the first electrocardiogram signal and values of the total quantity of values that correspond to the second electrocardiogram signal (see col. 2, lines 25-36). One of ordinary skill in the art at the time of the invention would have found it obvious to compare the values from the first and second ECG signals to understand which variations were attributed to the drug and which variations may be attributed to a problem in the heart, thereby improving signal processing and improve the accuracy of measuring alternans which in turn help detect abnormal cardiac repolarization (see '367, Abstract: 2nd sentence).

29. Regarding Claim 10, Arnold discloses a statistical analysis (see col. 8, lines 58-65). Arnold does not disclose the statistical analysis of the variation between pre-dose and post-dose ECG signals. DePasquale discloses statistically analyzing this variation (see col. 2, lines 43-48). Thus, it would be obvious to one of ordinary skill in the art at the time of the invention to perform a statistical analysis of any measurement acquired

from an ECG signal in order to understand which variations are significant and which ones are attributed to noise and other sources of error.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natasha N. Patel whose telephone number is 571-272-5818. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl H. Layno can be reached on 571-272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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December 10, 2007